PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Masakazu IMAMURA, et al.

Docket No: Q93771

Appln. No.: 10/541,615

Group Art Unit: 1644

Confirmation No.: 8296

Examiner: Jeffrey Olsen

Filed: July 7, 2005

For: C-GLYCOSIDE DERIVATIVES AND SALTS THEREOF

PETITION FOR ACCELERATED EXAMINATION UNDER 37 C.F.R. § 1.102(d) AND MPEP § 708.02 (VIII)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following is the statement of grounds for Accelerated Examination in the above-identified application.

A. A Petition to Make Special accompanied by the fee set forth in 37 C.F.R. § 1.17(h):

This document is a Petition to Make Special under 37 C.F.R. § 1.102(d); more particularly, a Petition for Accelerated Examination under MPEP § 708.02 (VIII). The fee of $130.00 required to afford this application special status is submitted herewith.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

08/29/2006 ATRAN1 00000106 10541615
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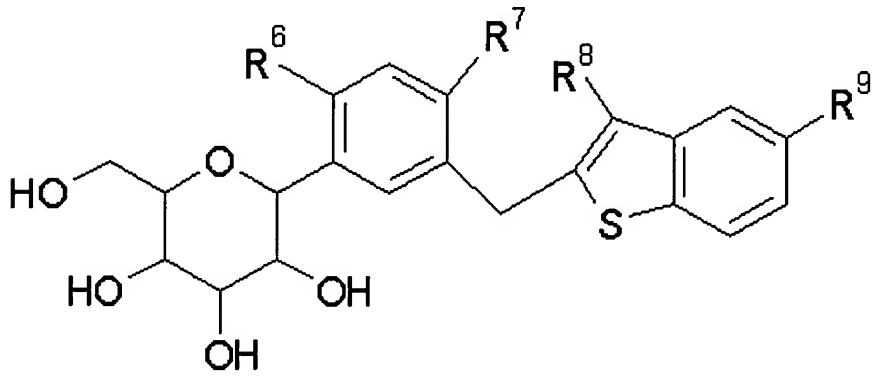
B. All of the claims are directed to a single invention

All of the claims in the present application are directed to a single invention, *i.e.*, a C-glycoside derivative of the following formula or a salt thereof:



wherein:

R^6 represents a hydrogen atom, halogen atom, -OH, -O-lower alkyl, -lower alkylene-OH, -O-lower alkylene-OH, -O-lower alkylene-NH_2, -COOH, -COO-lower alkyl, -O-lower alkylene-COOH, or -O-lower alkylene-COO-lower alkyl,

R^7 represents a hydrogen atom or halogen atom,

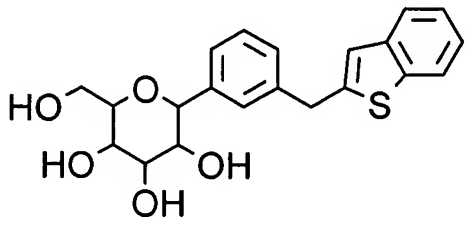
R^8 represents a hydrogen atom or -lower alkyl, and

R^9 represents a hydrogen atom, -lower alkyl, halogen atom, or -O-lower alkyl.

Applicant acknowledges that if the Office determines that all the claims presented are not obviously directed to a single invention, an election without traverse is a prerequisite to the grant of special status, and the established telephone restriction practice is to be followed.

C. A pre-examination search

Applicants have undertaken the required pre-examination search. In particular, Applicants have conducted a structural search of the STN registry files for compounds having the following skeleton:



One copy of the results of the structural search, including the required indication of field of search, is being submitted herewith for the Examiner's convenience.

D. One copy of each of the references deemed most closely related to the subject matter encompassed by the claims.

The following four references were identified in the search of the STN registry files:

Reference 1: WO2004/080990, published September 23, 2004,

Reference 2: WO2005/012326, published February 10, 2005,

Reference 3: WO2006/011502, published February 2, 2006, and

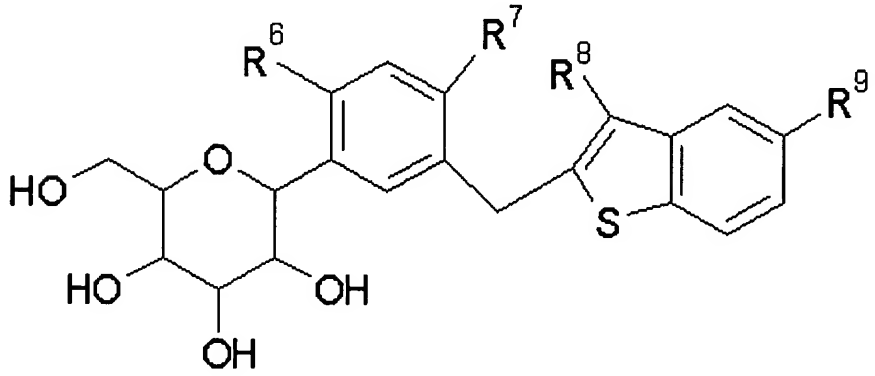
Reference 4: US2005/0233988, published October 20, 2005.

One copy of each reference is submitted herewith. Reference 1 is Applicant's corresponding PCT application. Reference Nos. 2-4 were made of record in the Information Disclosure Statement filed on August 9, 2006.

E. A detailed discussion of the references:

1. Brief Overview of the Present Invention

There is provided a C-glycoside derivative of the following formula or a salt thereof:



wherein:

R^6 represents a hydrogen atom, halogen atom, -OH, -O-lower alkyl, -lower alkylene-OH, -O-lower alkylene-OH, -O-lower alkylene-NH_2, -COOH, -COO-lower alkyl, -O-lower alkylene-COOH, or -O-lower alkylene-COO-lower alkyl,

R^7 represents a hydrogen atom or halogen atom,

R^8 represents a hydrogen atom or -lower alkyl, and

R^9 represents a hydrogen atom, -lower alkyl, halogen atom, or -O-lower alkyl, which are useful as Na^+-glucose cotransporter inhibitors, and particularly for treatment and prevention of various diabetes-related diseases, including insulin-dependent diabetes, insulin independent diabetes, insulin resistant diseases and obesity.

2. Explanation of Reference 1

Reference 1 is the international application corresponding to the present application. Reference 1 is not legally effective prior art against the present application.

3. Explanation of Reference 2

Reference 2 was published February 10, 2005, which is after the March 12, 2004 international filing date of Applicants' corresponding international application. Accordingly, Reference 2 is not legally effective prior art against the present application.

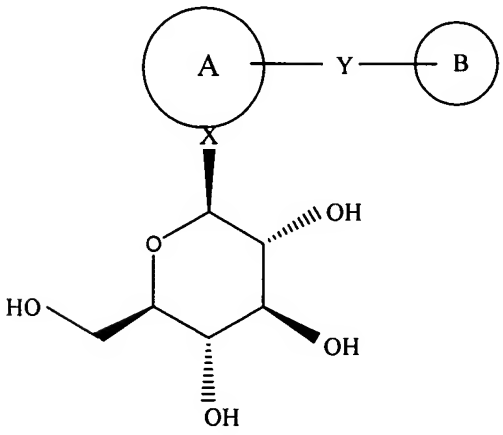
4. Explanation of Reference 3

Reference 3 was published February 2, 2006, which after the March 12, 2004 international filing date of Applicants' corresponding international application. Accordingly, reference 3 is not legally effective prior art against the present application.

5. Explanation of Reference 4

a. Explanation in comparison with subject application

Reference 4 discloses a compound of formula (I):



(I)

wherein Ring A and Ring B are one of the followings: (1) Ring A is an optionally substituted unsaturated monocyclic heterocyclic ring, and Ring B is an optionally substituted unsaturated monocyclic heterocyclic ring, an optionally substituted unsaturated fused heterobicyclic ring, or an optionally substituted benzene ring, (2) Ring A is an optionally

substituted benzene ring, and Ring B is an optionally substituted unsaturated monocyclic heterocyclic ring, or an optionally substituted unsaturated fused heterobicyclic ring wherein Y is linked to the heterocyclic ring of said fused heterobicyclic ring, or (3) Ring A is an optionally substituted unsaturated fused heterobicyclic ring, wherein the sugar moiety X-(sugar) and the moiety--Y-(Ring B) are both on the same heterocyclic ring of said fused heterobicyclic ring, and Ring B is an optionally substituted unsaturated monocyclic heterocyclic ring, an optionally substituted unsaturated fused heterobicyclic ring, or an optionally substituted benzene ring;

X is a carbon atom or a nitrogen atom; and

Y is --$(CH_2)_n$-- (wherein n is 1 or 2); a pharmaceutically acceptable salt thereof, or a prodrug thereof. (paragraphs 9 and 10)

In a preferred embodiment, Ring A is a benzene ring which may optionally be substituted by a substituent selected from the group consisting of a halogen atom, a lower alkyl group, a halo-lower alkyl group, a lower alkoxy group, and a phenyl group, and Ring B is a heterocyclic ring selected from the group consisting of thiophene, furan, benzofuran, benzothiophene, and benzothiazole, wherein the heterocyclic ring may optionally be substituted by a substituent selected from the following group: a halogen atom, a cyano group, a lower alkyl group, a halo-lower alkyl group, a phenyl-lower alkyl group, a lower alkoxy group, a halo-lower alkoxy group, a phenyl group, a halophenyl group, a lower alkylphenyl group, a lower alkoxyphenyl group, a thienyl group, a halothienyl group, a pyridyl group, a halopyridyl group, and a thiazolyl group. (paragraph 84)

Among the specific compounds disclosed are the following:

1-(β-D-glucopyranosyl)-4-chloro-3-(6-ethylbenzo- [b]thiophen-2-ylmethyl)benzene (paragraph 0125 and claim 21),

1-(β-D-glucopyranosyl)-3-(benzo[b]thiophen-2-ylmethyl)benzene (Example 3),

1-(β-D-glucopyranosyl)-4-chloro-3-(1-oxy-benzo[b]thiophen-2-ylmethyl)- benzene (Example 106),

1-(β-D-glucopyranosyl)-4-chloro-3-(1,1-dioxy-benzo[b]thiophen-2-ylmethyl)benzene (Example 107),

1-(β-D-glucopyranosyl)-4-chloro-3-(6-ethoxy-benzo[b]thiophen-2-ylmethyl)benzene (Example 129),

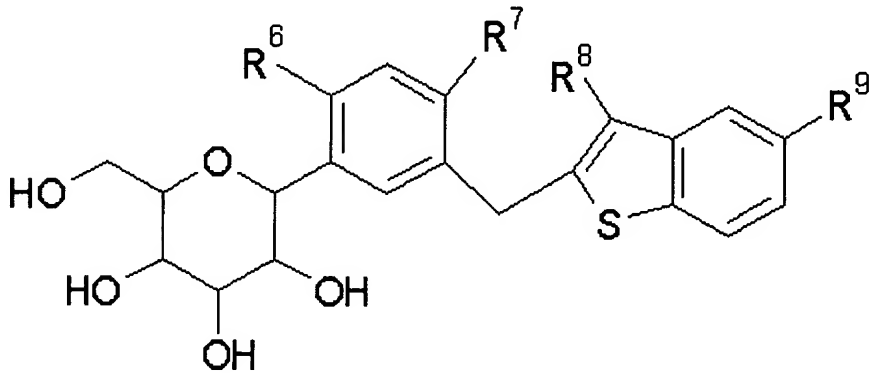
1-(β-D-glucopyranosyl)-4-chloro-3-(6-isopropyloxybenzo[b]thiophen-2-ylmethyl)benzene (Example 157),

1-(β-D-glucopyranosyl)-4-chloro-3-(6-ethylbenzo[b]thiophen-2-ylmethyl)benzene (Example 167),

1-(β-D-glucopyranosyl)-4-chloro-3-(6-n-propyloxybenzo[b]thiophen-2-ylmethyl)benzene (Example 174), and

1-(β-D-glucopyranosyl)-4-chloro-3-(6-(2-fluoroethyloxy)benzo[b]thiophen-2-ylmethyl)benzene (Example 175).

The invention of the present application, as described in the current claims provides a C-glycoside derivative of the following formula or a salt thereof:



wherein:

R^6 represents a hydrogen atom, halogen atom, -OH, -O-lower alkyl, -lower alkylene-OH, -O-lower alkylene-OH, -O-lower alkylene-NH_2, -COOH, -COO-lower alkyl, -O-lower alkylene-COOH, or -O-lower alkylene-COO-lower alkyl,

R^7 represents a hydrogen atom or halogen atom,

R^8 represents a hydrogen atom or -lower alkyl, and

R^9 represents a hydrogen atom, -lower alkyl, halogen atom, or -O-lower alkyl.

b. Explanation of the disclosure of Reference 4

Reference 4 discloses a genus of thousands of compounds that allegedly have inhibitory activity against sodium-dependent glucose transport being present in the intestine or kidney.

c. Comparison between the disclosure of the present application and the disclosure of Reference 4

Reference 4 discloses a genus of thousands of compounds that encompass the compounds or the present claims 13 and 14. Reference 4 also discloses, but does not claim, 1-(β-D-glucopyranosyl)-3-(benzo[b]thiophen-2-ylmethyl)benzene, which is encompassed by the present claims 13 and 14, when all of R^6, R^7, R^8, and R^9 are H.

None of the other specifically disclosed compounds falls within the present claim 13 or 14.

c.1. Comparison with the compound of Claim 13

Reference 4, discloses, but does not claim, 1-(β-D-glucopyranosyl)-3-(benzo[b]thiophen-2-ylmethyl)benzene, which is encompassed by the present Claim 13, when all of R^6, R^7, R^8, and R^9 are H.

However, the present Claim 13 has written description support in Applicants' Japanese priority document, which was filed prior to the filing date of the US provisional application to which Reference 4 claims priority. Therefore, Reference 4 can be antedated.

Furthermore, the US provisional application from which reference 4 claims priority does not specifically disclose any compounds wherein ring B in the formula (I) of reference 4 is a benzothiophene.

c.2. Comparison with the compound of Claim 14

Reference 4, discloses, but does not claim, 1-(β-D-glucopyranosyl)-3-(benzo[b]thiophen-2-ylmethyl)benzene, which is encompassed by the present Claim 14, when all of R^6, R^7, R^8, and R^9 are H.

However, the present Claim 13 has written description support in Applicants' Japanese priority document, which was filed prior to the filing date of the US provisional application to which Reference 4 claims priority. Therefore, Reference 4 can be antedated.

Furthermore, the US provisional application from which reference 4 claims priority does not specifically disclose any compounds wherein ring B in the formula (I) of reference 4 is a benzothiophene.

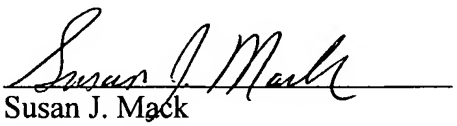
d. Reference 4 can be antedated, and, thus is not legally effective prior art against claims 13 or 14.

As shown in the chart in the attached Appendix, Claims 13 and 14 have 35 U.S.C. § 112 written description support in Applicants' Japanese priority document, JP-2003-070298. A copy of a certified English translation of the priority document is submitted herewith. Accordingly, claims 13 and 14 are entitled to the benefit of the March 14, 2003 filing date of JP-2003-070298, which is prior to the August 1, 2003 filing date of US 60/491,534, from which Reference 4 claims priority. Thus Reference 4 has been antedated and is not legally effective prior art against claims 13 or 14.

F. Conclusion

In view of the above remarks, Applicants submit that the requirements for accelerated examination have been met. Accordingly, grant of this petition is requested, respectfully.

Respectfully submitted,



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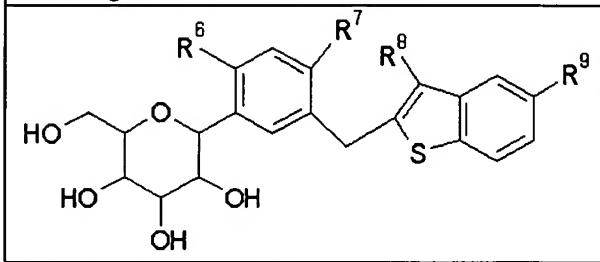
WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: August 23, 2006

Petition for Accelerated Examination
Under MPEP § 708.02 (VIII)
U.S. Application No. 10/541,615

Q93771

APPENDIX

Claims in USAN 10/541,615wherein:	Support in JP 2003-70297 (English Translation)
13. (new): A C-glycoside derivative of the following formula or a salt thereof:	Paragraphs 1, 4 and 6, collectively
	Compound no. 8 in Table 7; compound no. 31 in Table 11; the compounds in Table 12, rows 1-4; the compounds in Table 13, row 2, column 3, and row 3
R^6 represents a hydrogen atom, halogen atom, -OH, -O-lower alkyl, -lower alkylene-OH, -O-lower alkylene-OH, -O-lower alkylene-NH_2, -COOH, -COO-lower alkyl, -O-lower alkylene-COOH, or -O-lower alkylene-COO-lower alkyl,	Tbl. 7, Cpd. 8 (R^6= H); Tbl. 11, Cpd. 31 (R^6= H); Tbl. 12, row 1, col. 1 (R^6= OH); Tbl. 12, row 1, col. 2 (R^6=O(CH_2)$_2$OH); Tbl. 12, row 1, col. 3 (R^6=O(CH_2)$_2$$NH_2$); Tbl. 12, row 2, col. 1 (R^6=OCH_2COOH); Tbl. 12, row 2, col. 2 (R^6=OCH_2COOEt); Tbl. 12, row 2, col. 3 (R^6=COOH); Tbl. 12, row 3, col. 1 (R^6=COOEt); Tbl. 12, row 3, col. 2 (R^6=CH_2OH); Tbl. 12, row 3, col. 3 (R^6=OMe); Tbl. 12, row 4, col. 1 (R^6= Cl); Tbl. 12, row 4, col. 2 (R^6= F); Tbl. 12, row 4, col. 3 (R^6= H); Tbl. 13, row 2, col. 3; (R^6= H); Tbl. 13, row 3, col. 1 (R^6= H); Tbl. 13, row 3, col., 2 (R^6= H); Tbl. 13, row 3, col. 3 (R^6= H) Page 8, third full paragraph, defining R^5 - R^{11}: R^5 to R^{11} may be the same or different and individually represent a hydrogen atom, a lower alkyl, a halogen, a halogen-substituted lower alkyl, -OH, -O-lower alkyl, =O, -lower alkylene-OH, -lower alkylene-O-lower alkyl, -O-lower alkylene-O-lower alkyl, -O-lower alkylene-COOH, -O-lower alkylene-OH, -O-lower alkylene-C(=O)-O-lower alkyl, -O-lower alkylene-NH_2, -lower alkylene-O-C(=O)-lower alkyl, -COOH, -NO_2, -CN, -NH_2, -C(=O)-O-lower alkyl, a lower alkyl sulfonyl, an aryl sulfonyl, or a substituted amino substituted by lower alkyl, acyl, or -C(=O)-O-lower alkyl;

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	Paragraph 18, defining "lower" and "lower alkyl:" In the definition of the formulas in this specification, "lower" refers to a linear or branched carbon chain having 1-6 carbon atoms, unless otherwise specified. Accordingly, examples of "a lower alkyl" include linear or branched alkyls such as a methyl, ethyl, propyl, isopropyl, butyl, isobutyl, sec-butyl, tert-butyl, pentyl, isopentyl, hexyl, and isohexyl. Of these, C_{1-6} alkyls having 1-3 carbon atoms are preferable, and methyl and ethyl are particularly preferable. Paragraph 19, defining "a lower alkylene:" As "a lower alkylene", in addition to methylene, ethylene, propylene, and butylene, a branched lower alkylene may be used. Of these, methylene and ethylene are preferable, and methylene is particularly preferable. Paragraph 20, defining "a halogen atom:" Examples of "a halogen atom" include fluorine atom, chlorine atom, bromine atom, or iodine atom. Of these, fluorine atom, chlorine atom, and bromine atom are preferable.
R^7 represents a hydrogen atom or halogen atom,	Tbl. 7, Cpd. 8 (R^7= H); Tbl. 11, Cpd. 31 (R^7= H); Tbl. 12, row 1, col. 1 (R^7= H); Tbl. 12, row 1, col. 2 (R^7= H); Tbl. 12, row 1, col. 3 (R^7= H); Tbl. 12, row 2, col. 1 (R^7= H); Tbl. 12, row 2, col. 2 (R^7= H); Tbl. 12, row 2, col. 3 (R^7= H); Tbl. 12, row 3, col. 1 (R^7= H); Tbl. 12, row 3, col. 2 (R^7= H); Tbl. 12, row 3, col. 3 (R^7= H); Tbl. 12, row 4, col. 1 (R^7= H); Tbl. 12, row 4, col. 2 (R^7= H); Tbl. 12, row 4, col. 3 (R^7= Cl); Tbl. 13, row 2, col. 3; (R^7= H); Tbl. 13, row 3, col. 1 (R^7= H); Tbl. 13, row 3, col., 2 (R^7= H); Tbl. 13, row 3, col. 3 (R^7= H) Paragraph 20, defining "a halogen atom."

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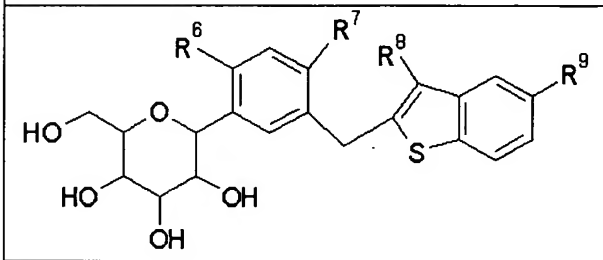
R^8 represents a hydrogen atom or -lower alkyl, and	Tbl. 7, Cpd. 8 (R^8= H); Tbl. 11, Cpd. 31 (R^8= CH_3); Tbl. 12, row 1, col. 1 (R^8= H); Tbl. 12, row 1, col. 2 (R^8= H); Tbl. 12, row 1, col. 3 (R^8= H); Tbl. 12, row 2, col. 1 (R^8= H); Tbl. 12, row 2, col. 2 (R^8= H); Tbl. 12, row 2, col. 3 (R^8= H); Tbl. 12, row 3, col. 1 (R^8= H); Tbl. 12, row 3, col. 2 (R^8= H); Tbl. 12, row 3, col. 3 (R^8= H); Tbl. 12, row 4, col. 1 (R^8= H); Tbl. 12, row 4, col. 2 (R^8= H); Tbl. 12, row 4, col. 3 (R^8= H); Tbl. 13, row 2, col. 3; (R^8= H); Tbl. 13, row 3, col. 1 (R^8= CH_3); Tbl. 13, row 3, col., 2 (R^8= CH_3); Tbl. 13, row 3, col. 3 (R^8= H) Paragraph 18, defining "lower alkyl."
R^9 represents a hydrogen atom, -lower alkyl, halogen atom, or -O-lower alkyl.	Tbl. 7, Cpd. 8 (R^9= H); Tbl. 11, Cpd. 31 (R^9= H); Tbl. 12, row 1, col. 1 (R^9= H); Tbl. 12, row 1, col. 2 (R^9= H); Tbl. 12, row 1, col. 3 (R^9= H); Tbl. 12, row 2, col. 1 (R^9= H); Tbl. 12, row 2, col. 2 (R^9= H); Tbl. 12, row 2, col. 3 (R^9= H); Tbl. 12, row 3, col. 1 (R^9= H); Tbl. 12, row 3, col. 2 (R^9= H); Tbl. 12, row 3, col. 3 (R^9=)H; Tbl. 12, row 4, col. 1 (R^9= H); Tbl. 12, row 4, col. 2 (R^9= H); Tbl. 12, row 4, col. 3 (R^9= H); Tbl. 13, row 2, col. 3; (R^9= CH_3); Tbl. 13, row 3, col. 1 (R^9= Cl); Tbl. 13, row 3, col., 2 (R^9= F); Tbl. 13, row 3, col. 3 (R^9= OMe) Paragraph 18, defining "lower alkyl." Paragraph 20, defining "a halogen atom."

APPENDIX

14. (new): A C-glycoside derivative of the following formula or a salt thereof :	Paragraphs 1, 4 and 6, collectively
	Compound no. 8 in Table 7; compound no. 31 in Table 11; the compounds in Table 12, rows 1-4; the compounds in Table 13, row 2, column 3, and row 3
wherein:	
R^6 represents a hydrogen atom, halogen atom, -OH, -OMe, $-CH_2-OH$, $-O-(CH_2)_2-OH$, $-O-(CH_2)_2-NH_2$, -COOH, -COOEt, $-O-CH_2-COOH$, or $-O-CH_2-COOEt$,	Tbl. 7, Cpd. 8 (R^6= H); Tbl. 11, Cpd. 31 (R^6= H); Tbl. 12, row 1, col. 1 (R^6= OH); Tbl. 12, row 1, col. 2 (R^6= $O(CH_2)_2OH$); Tbl. 12, row 1, col. 3 (R^6= $O(CH_2)_2NH_2$); Tbl. 12, row 2, col. 1 (R^6= OCH_2COOH); Tbl. 12, row 2, col. 2 (R^6= OCH_2COOEt); Tbl. 12, row 2, col. 3 (R^6= COOH); Tbl. 12, row 3, col. 1 (R^6= COOEt); Tbl. 12, row 3, col. 2 (R^6= CH_2OH); Tbl. 12, row 3, col. 3 (R^6= OMe); Tbl. 12, row 4, col. 1 (R^6= Cl); Tbl. 12, row 4, col. 2 (R^6= F); Tbl. 12, row 4, col. 3 (R^6= H); Tbl. 13, row 2, col. 3; (R^6= H); Tbl. 13, row 3, col. 1 (R^6= H); Tbl. 13, row 3, col., 2 (R^6= H); Tbl. 13, row 3, col. 3 (R^6= H) Paragraph 20, defining "a halogen atom."
R^7 represents a hydrogen atom or halogen atom,	Tbl. 7, Cpd. 8 (R^7= H); Tbl. 11, Cpd. 31 (R^7= H); Tbl. 12, row 1, col. 1 (R^7= H); Tbl. 12, row 1, col. 2 (R^7= H); Tbl. 12, row 1, col. 3 (R^7= H); Tbl. 12, row 2, col. 1 (R^7= H); Tbl. 12, row 2, col. 2 (R^7= H); Tbl. 12, row 2, col. 3 (R^7= H); Tbl. 12, row 3, col. 1 (R^7= H); Tbl. 12, row 3, col. 2 (R^7= H); Tbl. 12, row 3, col. 3 (R^7= H); Tbl. 12, row 4, col. 1 (R^7= H); Tbl. 12, row 4, col. 2 (R^7= H); Tbl. 12, row 4, col. 3 (R^7= Cl); Tbl. 13, row 2, col. 3; (R^7= H); Tbl. 13, row 3, col. 1 (R^7= H); Tbl. 13, row 3, col., 2 (R^7= H); Tbl. 13, row 3, col. 3 (R^7= H) Paragraph 20, defining "a halogen atom."
R^8 represents a hydrogen atom, or -Me, and	Tbl. 7, Cpd. 8 (R^8= H); Tbl. 11, Cpd. 31 (R^8= CH_3); Tbl. 12, row 1, col. 1 (R^8= H); Tbl. 12, row 1, col. 2 (R^8= H); Tbl. 12, row 1, col. 3 (R^8= H); Tbl. 12, row 2, col. 1 (R^8= H); Tbl. 12, row 2, col. 2 (R^8= H); Tbl. 12, row 2, col. 3 (R^8= H); Tbl. 12, row 3, col. 1 (R^8= H); Tbl. 12, row 3, col. 2 (R^8= H); Tbl. 12, row 3, col. 3 (R^8= H); Tbl. 12, row 4, col. 1 (R^8= H); Tbl. 12, row 4, col. 2 (R^8= H); Tbl. 12, row 4, col. 3 (R^8= H); Tbl. 13, row 2, col. 3; (R^8= H); Tbl. 13, row 3, col. 1 (R^8= CH_3); Tbl. 13, row 3, col., 2 (R^8= CH_3); Tbl. 13, row 3, col. 3 (R^8= H)

R^9 represents a hydrogen atom, -Me, halogen atom, or -OMe.	Tbl. 7, Cpd. 8 (R^9= H); Tbl. 11, Cpd. 31 (R^9= H); Tbl. 12, row 1, col. 1 (R^9= H); Tbl. 12, row 1, col. 2 (R^9= H); Tbl. 12, row 1, col. 3 (R^9= H); Tbl. 12, row 2, col. 1 (R^9= H); Tbl. 12, row 2, col. 2 (R^9= H); Tbl. 12, row 2, col. 3 (R^9= H); Tbl. 12, row 3, col. 1 (R^9= H); Tbl. 12, row 3, col. 2 (R^9= H); Tbl. 12, row 3, col. 3 (R^9= H); Tbl. 12, row 4, col. 1 (R^9= H); Tbl. 12, row 4, col. 2 (R^9= H); Tbl. 12, row 4, col. 3 (R^9= H); Tbl. 13, row 2, col. 3; (R^9= CH_3); Tbl. 13, row 3, col. 1 (R^9= Cl); Tbl. 13, row 3, col., 2 (R^9= F); Tbl. 13, row 3, col. 3 (R^9= OMe) Paragraph 20, defining "a halogen atom."